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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/101,132    06/30/98    TSUJI

S    760248F

EXAMINER
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HM22/0427

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EPPS, J	PAPER NUMBER
ART UNIT	

1635  
DATE MAILED:

04/27/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**Application No.  
**09/101,132**Applicant(s)  
**Tsuji et al.**Examiner  
**Janet Epps**Group Art Unit  
**1635**☒ Responsive to communication(s) filed on Jun 30, 1998☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**☒ Claim(s) 1-7 is/are pending in the application.Of the above, claim(s) 3 and 4 is/are withdrawn from consideration.☐ Claim(s) \_\_\_\_\_ is/are allowed.☒ Claim(s) 1, 2, and 5-7 is/are rejected.☐ Claim(s) \_\_\_\_\_ is/are objected to.☒ Claims 1-7 are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 5, 6, 7, drawn to a nucleic acid fragment, antisense nucleic acid, recombinant vector and a method of introducing said vector into "human body" and expressing said nucleic acid in said human body.

Group II, claim(s) 3, drawn to a protein.

Group III, claim(s) 4, drawn to an antibody .

2. The inventions listed as Groups I, II, and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The nucleic acid, recombinant vector and method of use of said vector of group I are patentably distinct subject matter from the protein of group II and the antibody of group III. The nucleic acid of group I is chemically, structurally, functionally, and materially distinct from the protein of group II, and the antibody of group III.

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3. During a telephone conversation with Gerald Murphy on 4/19/99 a provisional election was made without traverse to prosecute the invention of group I, claims 1, 2, and 5-7.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 3 and 4 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

5. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

*Claim Rejections - 35 USC § 101*

11. 35 U.S.C. 101 reads as follows:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

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Claim 7 is rejected under 35 U.S.C. 101 since the claimed invention is directed to non-statutory subject matter. The terminology used in these claims refer to a method of introducing a recombinant vector in to a human body, claims directed to or including within its scope a human (e.g. a human with the cellular material) will not be considered patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right of a human being is prohibited by the Constitution. See 1077 OG 24.

***Priority***

6. Receipt is acknowledged of a certified copy of the foreign application referred to in the oath or declaration. However, should applicant desire to obtain the benefits of the foreign filing date under 35 U.S.C. 119(a)-(d), applicant should also file a certified copy of the translation of the foreign application for such priority as required by 35 U.S.C. 119(b).

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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These claims are broadly drawn to a genus of antisense nucleic acid which inhibit the translation of spinocerebellar ataxia type 2 mRNA. The specification clearly fails to describe a representative number of species to allow one skilled in the art to envisage the structures of all members of the claimed genus. Furthermore, there is not sufficient information given regarding the structure of the target gene that may suggest potential targets sites to design antisense oligonucleotides which will result in the inhibition of translation of spinocerebellar ataxia type 2 mRNA.

Therefore, the specification does not describe the claimed compounds in such full and concise terms so as to indicate that the applicant had possession of these compounds at the time of filing of this application.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claim 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Pulst.

Pulst discloses the nucleotide sequence of the spinocerebellar ataxia type 2 (*SCA2*) gene as a direct submission to Genbank (Accession number: U70323). In addition, this sequence was further characterized by Pulst et al. (Nature Genetics, 1996, Nov. Vol. 14, p. 275), specifically

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Pulst et al. teach that the *SCA2* gene was identified on human chromosome 12 by genetic linkage studies of hereditary ataxias.

Pulst teaches each and every aspect of the instant invention, thereby anticipating applicant's claimed invention.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pulst and Levinson.

Pulst disclose the amino acid and DNA sequence encoding the Spinocerebellar ataxia type 2 protein, however Pulst do not disclose vectors comprising said DNA, host cells transformed with said vectors or methods of expressing the Spinocerebellar ataxia type 2 protein.

Levinson teaches methods of expressing a heterologous gene sequence comprising introducing the gene of interest into a vector with appropriate control elements to allow the expression of the gene, and transformation of the gene/vector construct into cells which would allow the expression of the gene and isolation of the protein product(p. 485-512).

Therefore, in view of the DNA sequence of Spinocerebellar ataxia type 2 disclosed by Pulst, and the knowledge available in the art for sub-cloning a gene of interest in a vector ,

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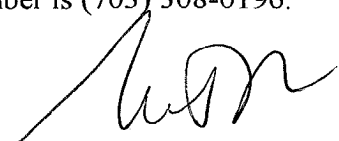
transformation of gene/vector construct into cells and expression of the gene of interest and isolation of the protein product in said cells as taught by Levinson, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of filing of the instant application to design vectors comprising the DNA sequence of Spinocerebellar ataxia type 2 as taught by Pulst, to transform the Spinocerebellar ataxia type 2/vector construct into cells, express the Spinocerebellar ataxia type 2 protein in said cells, and to isolate the Spinocerebellar ataxia type 2 protein from said cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps whose telephone number is (703) 308-8883. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax number for this group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet L. Epps, Ph.D.



NANCY DEGEN  
PRIMARY EXAMINER

April 26, 1999